Treatment-As-Usual Control Groups in Brief Alcohol Intervention Trials: A Systematic Review and Meta-Analysis

JACOB L. SCHARER, PH.D.,[a,*] JENNIFER S. FUNDERBURK, PH.D.,[a,b,c] MARTIN J. DE VITA, PH.D.,[a,b,d] YVETTE ROTHER, B.S.,[a] & STEPHEN A. MAISTO, PH.D.[a,b]

[a]*Veterans Affairs (VA) Center for Integrated Healthcare, Syracuse VA Medical Center, Syracuse, New York*
[b]*Department of Psychology, Syracuse University, Syracuse, New York*
[c]*Department of Psychiatry, University of Rochester, Rochester, New York*
[d]*Department of Behavioral Health, Brooke Army Medical Center, Joint Base San Antonio, Texas*

ABSTRACT. Objective: Brief alcohol interventions (BAIs) are evidence-based practices that can help reduce hazardous drinking among patients in medical settings. However, descriptions of the treatment-as-usual (TAU) control groups that BAIs are compared to in clinical trials often lack clarity and detail. This systematic review and meta-analysis quantified and compared descriptions of intervention and TAU control arms within reports of randomized controlled trials and examined whether treatment effects were affected by level of detail in narrative descriptions. **Method:** A systematic literature search to identify eligible articles was performed. Studies were rated on methodological quality, and the Template for Intervention Description and Replication (TIDieR) checklist was used to rate the level of clarity and detail included in descriptions of the intervention and TAU conditions in eligible articles. Data were extracted from articles for use in meta-analysis and meta-regression. **Results:** Twenty-one studies met inclusion criteria. Across the studies, TIDieR ratings for intervention arms were higher than ratings for control arms. BAIs were linked to reductions in drinks per week, heavy drinking episodes, and alcohol consequences over time when compared with TAU. TIDieR ratings for control groups were significantly associated with larger treatment effects on drinks per week and alcohol consequences but were not significant for heavy drinking episodes. **Conclusions:** This meta-analysis reiterated the effectiveness of BAIs in medical settings. Yet the lack of clarity in TAU descriptions raises concerns regarding the validity of BAI trials, suggesting need for more detailed reporting and use of the TIDieR guidelines for support. (*J. Stud. Alcohol Drugs, 83,* 934–943, 2022)

EXCESSIVE ALCOHOL USE is associated with a range of physical and mental health consequences and is a leading preventable cause of morbidity and premature death (Curry et al., 2018; Rehm et al., 2003). Addressing hazardous alcohol use in primary care and other healthcare settings (e.g., emergency departments) has been a focus of secondary intervention efforts because of the potential to improve access to care and early treatment (Kaner et al., 2009). In particular, there is a large research consensus that brief alcohol interventions (BAIs) delivered in healthcare settings are efficacious for reducing hazardous drinking, with numerous studies showing that BAIs help patients reduce their drinking (Kaner et al., 2009, 2018) relative to patients in control groups. These findings have led to guidelines from the U.S. Preventative Services Task Force recommending regular screening of adults for unhealthy alcohol use and administering BAIs to those who screen positive. Similar guidelines have been issued by the American Academy of Pediatrics (Levy et al., 2016), recommending regular screening and brief intervention for adolescents.

Like other interventions tested in healthcare settings, BAIs are frequently compared to treatment-as-usual (TAU) control groups to estimate their efficacy (Kaner et al., 2018; Kazdin, 2015). Various labels are used in the literature for these types of control groups (hereafter referred to as TAU), such as "usual care" and "standard care." TAU control groups have several distinct advantages when used in clinical research compared with other types of control groups, including meeting the requirements of the ethical conduct of research, reducing participant attrition, improving internal validity (controlling for possible nonexperimental intervention-specific factors that may be related to outcomes), and improving satisfaction of clinicians providing the interventions as well as individuals who read the results of the research because of increased ethical acceptability (Kazdin, 2003).

Despite the contributions that the use of TAU groups have made to the design of intervention clinical trials in

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*Correspondence may be sent to Jacob L. Scharer at the VA Center for Integrated Healthcare, Syracuse VA Medical Center, 800 Irving Ave (116C), Syracuse, NY 13210, or via email at: jacob.scharer@va.gov.

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healthcare settings, some concerns have been noted in the literature related to how TAU groups are described in the literature and how differences in TAU characteristics may affect trial results. Previous reviews have noted that TAU characteristics are frequently unclear, with numerous behavioral intervention studies having inadequate or missing TAU condition descriptions (Cape et al., 2000; Freedland et al., 2011; Wampold et al., 2011). Literature reviews have also revealed significant heterogeneity in what is labeled as TAU in randomized controlled trials of behavioral interventions for anxiety and depression (Wampold et al., 2011; Watts et al., 2015). They have also noted differences in outcomes based on the types of control conditions used in trials of behavioral interventions for college student alcohol use (Scott-Sheldon et al., 2012), such that studies with active control groups tended to have smaller treatment effects compared with wait-list or assessment-only conditions. Such shortcomings in the characterization of control groups may result in problems for several reasons. First, if control groups are not adequately described, it is impossible to determine the degree to which the experimental intervention was distinct from the control in hypothesized "active ingredients" that purportedly are specific to the experimental intervention. Therefore, what a trial is designed to test may not be what is actually tested. Additionally, other research teams would likely be impeded considerably in efforts to independently replicate any clinical trial in question. Further, there is a related difficulty in specifying the conditions under and the context in which the original intervention effects were found. Ultimately, these problems affect intervention implementation because they may lead to errors in determining what interventions are candidates for implementation, and if there is an effort to implement an intervention, errors could be made as a result of absent or misleading prior data.

As a result of the research and clinical practice consequences of poor specification of experimental and control conditions, reporting guidelines such as the Consolidated Standards for Reporting Trials (CONSORT) statement have stressed the importance of including key information when describing interventions included in research trials (Schulz et al., 2010). To further this guidance and assist with reporting of necessary methodological information about study conditions, the Template for Intervention Description and Replication (TIDieR; Hoffman et al., 2014) guidelines were developed, which specify 12 key methodological domains that should be described when reporting the results of intervention trials. The TIDieR checklist was devised as a tool to evaluate descriptions of interventions. Because TAU control conditions are also "active" interventions functioning as control comparisons (Kazdin, 2003), the elements included in the TIDieR checklist can also be applied to TAU conditions. For example, one systematic review used the TIDieR checklist to examine adequacy of reporting in TAU control groups in pediatric clinical trials (Yu et al., 2018).

The literature surrounding the efficacy of BAIs is decades old and has received several excellent systematic reviews in recent years (e.g., Kaner et al., 2018). However, no review has focused on the control groups that have been used, their descriptions, and what these factors suggest about the current consensus that BAIs are efficacious and effective and that their implementation should be promoted. Therefore, it seems essential to examine the quality of reporting on TAU groups used in the BAI research literature. Thus, we present a systematic review and meta-analysis examining the literature on BAIs in healthcare settings, focusing on randomized controlled trials that use a TAU (or equivalent terminology) control group. We aimed to (a) quantitatively test the hypothesis that more attention is given to describing intervention groups compared with TAU groups by using the TIDieR to rate the level of clarity and detail included in narrative descriptions of treatment arms presented in the articles, and (b) reaffirm efficacy of BAIs relative to TAU in medical settings using meta-analysis and examine the degree to which interpretation of results is affected by the level of detail included in narrative descriptions of TAU within the reviewed articles.

Method

Information sources/search/study selection

This systematic review and meta-analysis was guided by PRISMA guidelines (Page et al., 2021). A systematic literature search was conducted for articles published before October 2019 within the PubMed, PsycINFO, and CINAHL databases. The literature search used the terms "alcohol*" or "drink*" in combination with either sbirt, brief, short, abbreviated, intervention, treatment, therapy, counseling, counselling, or psychotherapy and primary care, general practice, primary healthcare, family medicine, family practice, internal medicine, family physician, family doctor, gp, or pc. Abstracts describing brief interventions for alcohol in healthcare settings were reviewed (by two authors and trained research assistants) to identify potentially eligible articles. Ninety full-text articles were then reviewed for eligibility criteria. Reference lists from included studies were also manually searched for eligible studies, and we are grateful to an external reviewer for identifying one eligible study that was not identified by our literature search (Monti et al., 1999).

Eligibility criteria

Eligible full-text articles examined BAIs for any age group in a healthcare setting. Eligible studies (a) tested a brief intervention that targeted alcohol use (b) through a randomized controlled trial (RCT) compared the intervention to TAU, and (c) assessed an alcohol-related outcome. Additional eligibility criteria included (d) being conducted in

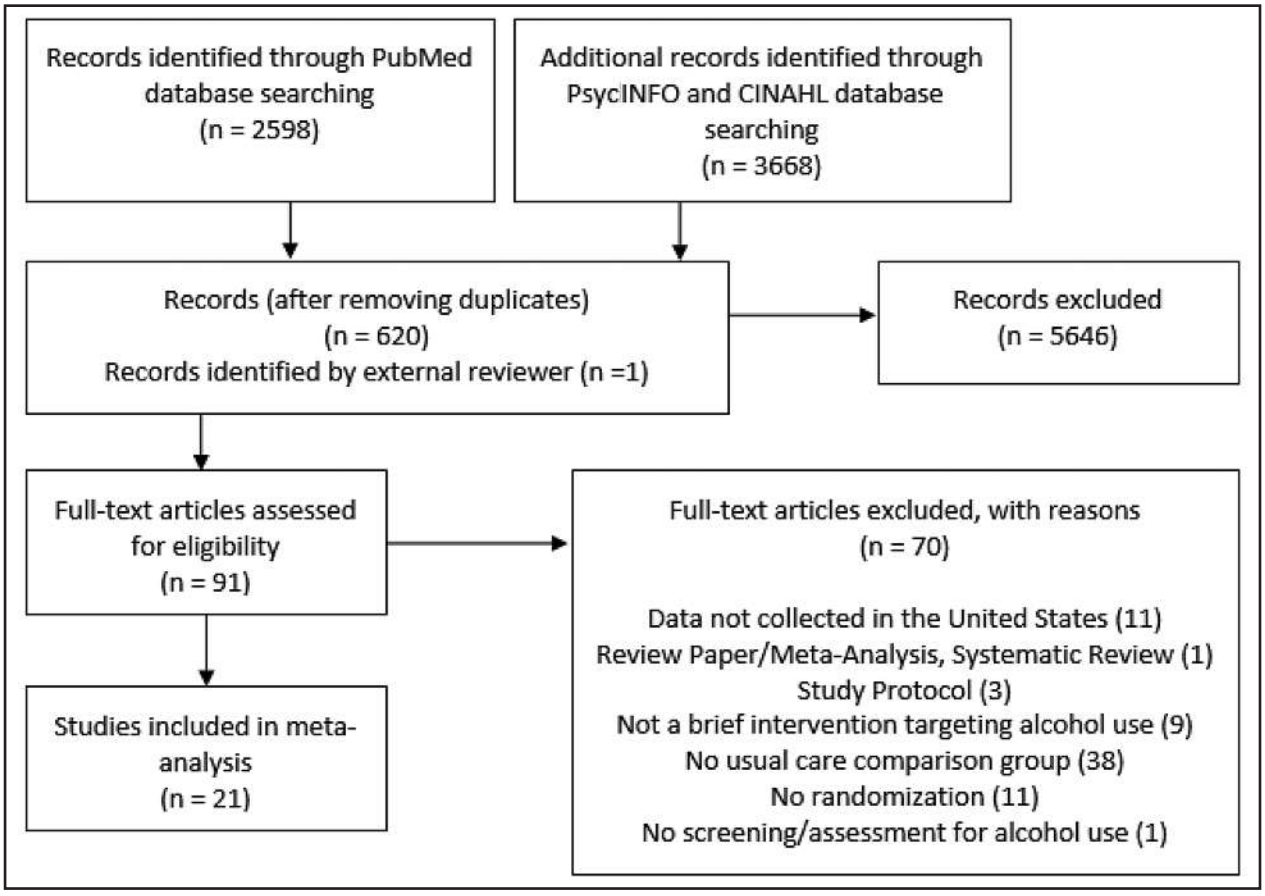

FIGURE 1. Study flow diagram

the United States, (e) written in English, and (f) published in a peer-reviewed journal. In addition, studies were excluded if they were solely a secondary analysis of another RCT that was not focused on alcohol outcomes, or solely focused on implementation. For this review, we included studies that used any modality of intervention (e.g., individual, phone, online). After removing duplicates and studies not meeting criteria, 20 articles were included for rating, with one added later at the suggestion of an external reviewer. The most common reasons for exclusion were a not having a TAU comparison group (n = 38), no randomization (n = 11), and data collection outside of the United States (n = 11). See Figure 1 for a full list of reasons for exclusion.

Methodological quality

To assess the methodological quality of studies, we used the Methodological Quality Scale (MQRS; Miller & Wilbourne, 2002). The scale consists of 12 items that rate different components of study quality, with lower scores corresponding to lower quality. The total score, after adding all subcategories, ranges from 0 to 17. A study with a total score between 14 and 17 represents a well-designed study (Miller & Wilbourne, 2002). All included studies were rated independently by two of the authors. Agreement between raters was high (P_a = 95.8%); all discrepancies in ratings were resolved through discussion.

TIDieR ratings

Two independent raters evaluated eligible studies using a modified TIDieR rating scale (Yu et al., 2018). Intervention and control arms were rated separately; for studies that included more than one intervention arm, each arm was rated separately and we used the mean of the ratings. Percent agreement between raters on TIDieR items for the present study was high (P_a = 96.6%); all discrepancies in ratings were resolved through discussion.

The TIDieR was designed to assess the quality of description of the study conditions (Hoffman et al., 2014) and contains 12 items that describe key features of the intervention. Yu et al. (2018) adapted this checklist by separating the intervention provider component into the following two items: (a) "do the authors describe who provided the treatment," and (b) "do the authors describe any training given to individuals providing the treatment." They further added

Table 1. TIDieR item descriptions and frequency of reporting

Item	Description	Studies reporting this item: Control groups *n* (%)	Studies reporting this item: Intervention group *n* (%)
TIDieR 1[a]	Do authors provide a name or phrase that describes the arm?	15 (85.7%)	21 (100%)
TIDieR 2[a]	Do authors describe any rationale, theory, or goal of the elements essential to the arm?	5 (23.8%)	21 (100%)
TIDieR 3	Do authors cite any reference for their justification?	2 (9.5%)	21 (100%)
TIDieR 4[a]	Do authors describe any physical or informational materials used?	14 (66.6%)	18 (85.7%)
TIDieR 5[a]	Procedures: Do authors describe the procedures, activities, or processes used?	15 (71.4%)	21 (100%)
TIDieR 6[a]	Do authors describe who provided the intervention?	11 (52.4%)	20 (95.2%)
TIDieR 7	Do authors describe the expertise, background, or any specific training given?	5 (23.8%)	20 (95.2%)
TIDieR 8[a]	Do authors describe the modes of delivery?	4 (19%)	20 (95.2%)
TIDieR 9[a]	Do authors describe the types of locations where the intervention occurred?	8 (38.1%)	17 (80.9%)
TIDieR 10[a]	Do authors describe the number of times the intervention was delivered and over what period of time?	2 (9.5%)	21 (100%)
TIDieR 11	If the intervention was planned to be personalized, titrated, or adapted, then did they describe what, when, and how?	0 (0%)	12 (57.1 %)
TIDieR 12	If the intervention was modified, did they describe the changes? This includes protocol deviations due to adherence.	1 (4.7%)	9 (42.8%)

Notes: TIDieR = Template for Intervention Description and Replication. [a]Item was included in the revised eight-item TIDieR score used for exploratory analyses.

an item assessing whether rationale is given for choice of intervention or control group. The items evaluating study modification and adherence and fidelity were combined into one item that explicitly assessed the presence, or lack thereof, of any deviation for a priori study/intervention protocol. Descriptions of all items in the modified checklist used in the present study are included in Table 1.

We modified our interpretation of certain items on the TIDieR rating scale if a study was examining an e-intervention, to ensure that these types of interventions could be assessed accurately given that some of the original criteria were not applicable to e-interventions. To score positively on Item 6 ("do authors describe who provided the intervention"), the article would have had to describe what device the participants were using (e.g., their own smartphone, computer in office, tablet). For Item 7 ("do authors describe the expertise, background, or any specific training given"), we assessed if instructions given to participants were described for using the device and/or using the e-intervention. Further, Item 9 ("do authors describe the types of locations where the intervention occurred") had to address where participants accessed the intervention (e.g., at home, in office, etc.).

Data analysis plan

Descriptive statistics were computed for characteristics of the reviewed studies (Table 2). Total TIDieR scores for TAU and intervention groups were calculated, as well as TIDieR eight-item scores, which included only the items relevant to control groups. Nonparametric Spearman correlations or analyses of variance (ANOVAs; depending on variable type) were conducted to analyze bivariate relationships between TIDieR ratings and study characteristics. IBM SPSS Statistics for Windows, Version 25 (IBM Corp, Armonk, NY), was used for data management, descriptive statistics, bivariate correlations, and ANOVA calculations.

Meta-analysis and meta-regression were conducted using Comprehensive Meta-Analysis (CMA v3) software (Borenstein et al., 2011). Hedges' *g* was used as the effect size estimate for all analyses, and analyses were specified such that a larger positive Hedges' *g* indicated a greater treatment effect in favor of the intervention group. All outcomes were coded such that larger effect sizes indicated improved outcomes favoring the intervention group. First, to confirm that the studies in this review followed the pattern of other reviews (i.e., BAIs outperform TAU), random-effects models comparing intervention and TAU groups were conducted for the three most common alcohol outcomes: number of drinks per week (drinks per other units of time were also included in this analysis; e.g., drinks per month), binge/heavy drinking episode frequency (heavy drinking days also included in analysis), and alcohol consequences/alcohol problems. Next, we used meta-regression to determine if TIDieR ratings (for control groups and intervention groups) were associated with treatment effect sizes. Given that there were a variety of follow-up points used among the included studies, we used the earliest follow-up point for each included study for the present analyses (earliest time points ranged from 2 to 12 months for the included studies). This approach was selected because of prior research showing that effects of BAIs are most efficacious for improving alcohol outcomes at earlier

Table 2. Characteristics of included studies

Study	Setting and participants	Control group label	TIDieR ratings		MQRS
			TAU	Intervention	
Babor et al., 2006	Primary care Adult patients	Usual care	6	10	13
Boekeloo et al., 2004	Primary care Adolescent patients	Usual care	7	11	14
Cucciare et al., 2013	Primary care Adult patients	Treatment as usual	3	10	12
Curry et al., 2003	Primary care Adult patients	Usual care	3	12	12
D'Amico et al., 2008	Primary care Adolescent patients	Care as usual	1	11	9
D'Amico et al., 2018	Primary care Adolescent patients	Usual care	2	11	12
D'Onofrio et al., 2012	Emergency department Adult patients	Standard care	5	1	13
Fleming et al., 1997	Primary care Adult patients	Control group	5	12	16
Fleming et al., 1999	Primary care Adult patients	Control group	3	11	14
Fleming, et al., 2004	Primary care Adult patients	Usual care	4	11	16
Fleming et al., 2008	Obstetrician Adult patients	Usual care	4	11	14
Fleming et al., 2010	College student health Adult patients	Usual care	3	11	14
Forray et al., 2018	Reproductive health Adult patients	Enhanced usual care	4	9	13
Maisto et al., 2001	Primary care Adult patients	Standard care	7	10.5	13
Monti et al., 1999	Emergency department Older adolescents (18–19 years)	Standard care	5	10	13
Ockene et al., 1999	Primary care Adult patients	Usual care	5	11	12
Rose et al., 2017	Primary care Adult patients	No IVR control	2	8	12
Saitz et al., 2007	Medical inpatient Adult patients	Usual care	3	10	12
Schaus et al., 2009	College student health Adult patients	Control	3	11	10
Senft et al., 1997	Primary care Adult patients	Usual care	3	11	14
Stein et al., 2009	Emergency department Adult patients	Standard care	7	10	10

Notes: For studies with multiple intervention groups, the mean Template for Intervention Description and Replication (TIDieR) rating is displayed. TAU = treatment as usual; MQRS = Methodological Quality Rating Scale. Higher TIDieR scores indicate inclusion of more key features of study arms. MQRS scores between 14 and 17 indicate well-designed studies.

follow-up points (Kaner et al., 2009). Statistical information was extracted from the reviewed studies by two raters to ensure accuracy of data. For data presented graphically (e.g., charts), a validated data extraction software (WebPlotDigitizer v.4) was used to obtain values (Drevon et al., 2017; Rohatgi, 2017).

Results

Study descriptive characteristics

A total of 21 randomized controlled trials met inclusion criteria for the present review. A majority of studies were conducted in primary care settings (n = 13), whereas fewer were conducted in emergency departments (n = 3), college student health clinics (n = 2), a reproductive health clinic (n = 1), an obstetric clinic (n = 1), and a medical inpatient unit (n = 1). Most studies examined BAIs for adult patients (n = 17), although several were provided to adolescents (n = 4). The modality of intervention used in the included studies was primarily individual in-person sessions (n = 18), whereas fewer studies used web- or computer-based interventions (n = 2) or phone-based interventions (n = 1); one study included in-person and computer-based interventions. Four studies included two intervention arms (Boekeloo et al., 2004; Forray et al., 2019; Maisto et al., 2001; Stein et

al., 2009). See Table 2 for details on characteristics of the included studies.

Methodological quality ratings

The mean methodological quality rating of the reviewed studies was 12.76. Seven of the 20 studies reviewed were assigned ratings greater than or equal to 14, which is indicative of a well-designed study according to the developers of the MQRS. However, all studies were assigned ratings of 10 or greater (range: 10–16), suggesting relatively good methodological quality amongst the included studies.

TIDieR ratings

TIDieR ratings for intervention arms were significantly higher than ratings for control arms across the included studies; the mean number of TIDieR checklist items reported was 4.05 (SD = 1.75, range: 1–7) for TAU arms and 10.5 (SD = 1.15, range: 8–12) for intervention arms. Other characteristics not associated with control group TIDieR ratings were treatment setting (F = 0.07, p = .797; primary care vs. other healthcare settings), age group (F = 0.50, p = .488; adult vs. adolescent), mode of intervention (F = 1.17, p = .294; in-person intervention vs. digital or phone based), or impact factor of journals in which the studies were published (r = .20, p = .395). Control group TIDieR ratings of included studies were also not significantly correlated with their intervention group TIDieR ratings (r = -.08, p = .943).

Meta-analysis and meta-regression

Random-effects meta-analysis was used to compare intervention and TAU conditions in the included studies. An examination of Egger bias tests and funnel plots for analyses of all three outcomes suggests that publication bias was not indicated; bias tests for all outcomes were not significant [drinks per week (t = 1.15, p = .13), binge drinking (t = 0.11, p = .46), alcohol consequences (t = 0.080, p = .44)]. Results indicated that participants receiving a BAI showed greater reductions over time on drinks per week (Hedges' g = 0.191, 95% CI [0.099, 0.282], p < .001), heavy drinking episodes (Hedges' g = 0.188, 95% CI [0.117, 0.259], p < .001), and alcohol consequences (Hedges' g = 0.090, 95% CI [0.024, 0.156], p = .008) compared with patients who received TAU (see Supplemental Figures A–C for more detail). Significant heterogeneity was observed across effect sizes for drinks per week, heavy drinking episodes, and alcohol problems. A moderate level of heterogeneity was present based on I^2 values across comparison effect sizes for drinks per week, $Q(15) = 54.46$, $p < .001$, $I^2 = 72\%$, $\tau = .15$, and binge drinking, $Q(12) = 20.63$, $p = .056$, $I^2 = 42\%$, $\tau = .08$. Substantial heterogeneity was not detected for alcohol consequences, $Q(9) = 9.634$, $p = .381$, $I^2 = 7\%$, $\tau = .28$.

Meta-regression results indicated that control group TIDieR ratings were significantly associated with greater treatment effect sizes on drinks per week (Z = 2.27, p = .023; Figure 2) and alcohol consequences (Z = 2.16, p = .031; Figure 3). That is, studies with more detailed TAU descriptions had larger effect sizes favoring the intervention group for improvements in drinking outcomes. In contrast, this association was not significant for heavy drinking episodes (Z = 0.57, p = .65). When examining moderation effects of TIDieR ratings for intervention groups, TIDieR ratings were significantly positively associated with treatment effects sizes for the outcome of drinks per week (Z = 3.069, p = .002). That is, studies with more detailed intervention condition descriptions tended to have greater reductions in drinks per week. No significant moderating effects of intervention group TIDieR ratings were present for the outcomes of heavy drinking (Z = .433, p = .665) or alcohol consequences (Z = -1.95, p = .051).

When examining specific TIDieR items, some items were more commonly present in descriptions of intervention groups than in TAU group descriptions (Table 1). Because the TIDieR items vary in their relevance to control groups, as the checklist was initially developed to assess descriptions of experimental arms, we conducted post hoc exploratory analyses to determine whether TIDieR items with less relevance to control groups might be affecting results.

We identified the items that were most relevant to TAU control groups and created a modified score for each study using eight items from the original TIDieR checklist and excluding four checklist items with the least relevance to TAU control groups. This was determined through discussion amongst three of the authors and confirmed with two additional doctoral-level researchers. Using the revised TIDieR checklist, mean ratings for control (M = 3.6, SD = 0.88, range: 1–7) and intervention (M = 7.59, SD = .66, range: 6–8) arms were less disparate. Bivariate analyses and meta-regression results using the revised TIDieR scores did not differ substantially from results using the complete checklist (i.e., significant results remained significant and no additional analyses rose to significance.)

Discussion

The results of this systematic review and meta-analysis reaffirm that BAIs provided to patients in medical settings are associated with greater improvements in drinking outcomes compared with TAU, with a majority of studies reporting small to moderate effect sizes and rated with high levels of methodological quality. However, the data also suggest that interpreting these differences is extremely difficult given the level of description of TAU groups in the included articles, which was consistently less detailed than descriptions of intervention groups based on our use of the TIDieR checklist to quantify these differences. Overall, this lack of

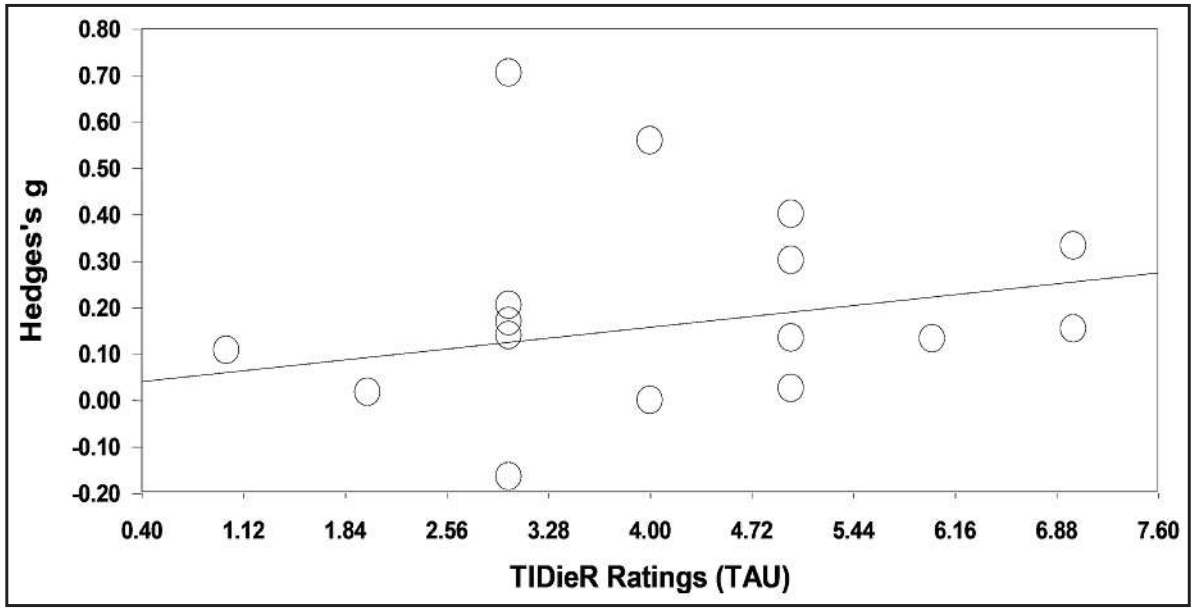

FIGURE 2. Meta-regression results for the association between treatment effect size (Hedges' *g*) and Template for Intervention Description and Replication (TIDieR) ratings for treatment-as-usual (TAU) groups for the outcome of drinks per week

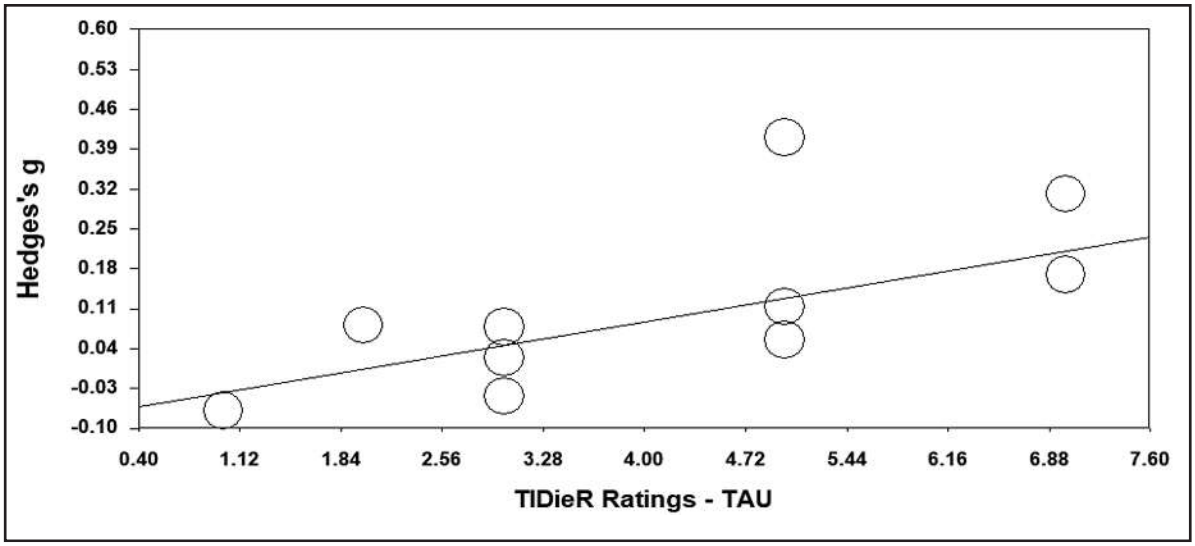

FIGURE 3. Meta-regression results for the association between treatment effect size (Hedges' *g*) and Template for Intervention Description and Replication (TIDieR) ratings for treatment-as-usual (TAU) groups for the outcome of alcohol problems

detail weakened both internal and external validity of the findings.

Although the meta-analysis portion of the present study found that studies with more detailed narrative descriptions of TAU groups found larger treatment effects on drinking outcomes, the mean TIDieR rating achieved within TAU groups was still nearly 8 points from the highest possible TIDieR rating. In the reviewed studies, few key details were consistently included in descriptions of TAU study arms across the majority of BAI trials, which makes it difficult to distinguish the active components of the experimental intervention that are hypothesized to result in changes in alcohol use outcomes. Thus, this lack of detail weakens the internal validity of BAI trials. External validity is also weakened by the lack of key descriptors of TAU groups, as replication of the reviewed BAI trials would be difficult, if not impossible, given the degree of information provided in most studies. This also creates difficulty in understanding the specific conditions and context in which BAIs are likely to be effective, given the lack of specificity of these aspects of TAU. Thus, a

thorough understanding of what constitutes TAU is essential to interpreting the effects of BAIs and evaluating them in relation to services that are already being offered in healthcare settings. For example, in the VA all patients are screened yearly for hazardous alcohol use, and healthcare providers are required to provide some form of brief intervention or advice in the event of a positive screen. This is an important contextual detail for understanding the effects of a novel or alternative BAI in comparison to TAU, and procedures for screening certainly differ within other healthcare settings (i.e., more or less alcohol-related care may be provided).

One might argue that TIDieR was originally geared toward evaluating the active intervention conditions of RCTs and consequently some of the items, such as details of personalization or adaptation, modifications or deviations from the intervention protocol, and citations/references justifying use of the intervention, are potentially less applicable to control groups. These items were most often absent from TAU descriptions (less than 10% of studies) in this review. To explore the potential implications of some TIDieR items being less relevant to TAU conditions, we conducted additional exploratory meta-regression analyses using an abbreviated eight-item TIDieR score that was calculated without four items that the research team determined were potentially less relevant to control conditions. However, when repeating our analyses with the abbreviated score, our results did not change substantively, as significant results from our initial analysis remained significant, and no additional analyses rose to significance.

Although our results indicate that studies with more detailed TAU descriptions had larger treatment effects on drinking outcomes, it is difficult to determine the mechanism(s) that might explain this finding, as the TIDieR ratings that served as a moderator variable were based solely on how much detail was included in the published articles that were reviewed and do not necessarily reflect the actual structure and content of TAU at the respective study sites. Thus, it is not possible to determine why studies with more detailed TAU descriptions showed larger treatment effects; instead, we hope to highlight the importance of including adequate detail on TAU in BAI study reports. Of note, there was a lack of variability within the TIDieR ratings for TAU conditions in the present review, as most of the studies were on the lower range. This restriction in range also could potentially explain the finding that studies with more detailed TAU descriptions were associated with larger effect sizes, yet no association was found between TIDieR ratings and methodological quality (as indicated by the MQRS), suggesting that the larger treatment effects are not attributable to an overall higher degree of methodological rigor among some studies. TIDieR items, such as who provided the intervention, modes of delivery, and number/length of time were also not consistently present, limiting the ability to understand the impact of the lack of description on the results and to identify a potential mechanism(s) underlying this association.

One potential explanation for this association is that some of the included trials used variations of TAU conditions such as "enhanced" usual care in which patients received an element of care that is typically not a part of routine care in the clinical setting, which necessitated more descriptions of the TAU group and may have resulted in higher TIDieR ratings in the present review. Similarly, if trials used simulated TAU conditions in which they have more knowledge of and control over elements that are present in usual care, allowing them to ensure treatment differentiation between the BAI and what is offered in TAU, this could have resulted in more pronounced treatment effects. It is also important to note that the level of detail included in TAU descriptions can be influenced by other factors that are outside the scope of this review, such as journal requirements or availability of funding, which adds to the difficulty of identifying an explanation for this association.

Results of the present review should be interpreted in light of several limitations. Importantly, the TIDieR checklist was not specifically designed for use with control/comparison groups. Although we used a modified version of the measure (Yu et al., 2018) that was adjusted to better assess control group characteristics, it is possible that using the TIDieR checklist to evaluate manuscript elements outside of its original purpose could have affected our results. We attempted to alleviate this potential for bias by identifying a limited set of TIDieR items that were applicable to both intervention and control groups. However, substituting these revised TIDieR scores in our meta-analyses did not significantly alter results. In addition, although the TIDieR has some limitations in terms of its applicability to control groups, it is the only established and validated checklist we are aware of that includes essential elements for reporting on intervention arms. Further, alternatives such as the CONSORT criteria do not specifically focus on content of intervention conditions (CONSORT has only one item assessing reporting of intervention details). As mentioned previously, the TIDieR assesses only adequacy of reporting on intervention conditions, in this case TAU conditions, and thus, TIDieR ratings do not necessarily reflect the nature of actual TAU at a given study site. An additional limitation is related to the generalizability of the results of this review. In particular, we chose to include only studies conducted in healthcare settings in the United States; thus, the results of this review may not generalize to studies of BAIs conducted in other settings or in other countries. In addition, this review includes only published studies identified via the literature review process (described in the Method section) and thus could potentially be subject to publication bias.

Despite these limitations, the present review has implications for future research and can inform guidance for design

and reporting of BAI trials. By attending to key aspects of control groups when reporting on randomized controlled trials, researchers may be able to ameliorate concerns related to validity. Tools such as the TIDieR checklist can simplify this task for researchers and help ensure that they are including key features of intervention arms that are essential to replicability; using the TIDieR as intended when preparing, submitting, or reviewing manuscripts can help ensure that key details of all study arms are present. Researchers could also potentially use the TIDieR checklist during the process of planning research studies so that they can ensure that data are collected regarding each TIDieR component during the research process. For example, a majority (90%) of the reviewed studies did not report the frequency and duration of treatment sessions for their TAU groups (TIDieR Item 10). With prior planning, these data could be collected (e.g., through a medical record data pull) so that researchers can determine the average number of visits patients had with their usual care providers during the study period. Consideration of reporting standards early in the planning process allows for data collection procedures such as these to be included in grant applications, study protocols, and internal review board approvals.

Collecting and reporting more complete information regarding TAU conditions is also advantageous to researchers conducting clinical trials. These data can be used to better understand the main findings of a trial, and presenting sufficient details regarding the typical clinical context in which a trial is conducted can lend weight and validity when interpreting its potential implications. Collecting detailed information about TAU could also help explain unexpected findings. For example, failing to find a significant effect of an intervention (compared with TAU) can occur if elements of said intervention are present in the TAU condition. With sufficient data regarding TAU, researchers can determine which such elements were present in usual care or they may be able to use this information to plan or control for such confounds before conducting a trial. Aside from advantages for researchers conducting individual trials, reporting adequate details of TAU facilitates and strengthens the cumulative science such that future reviews and meta-analyses have sufficient data to draw substantive conclusions about the findings of studies across varying contexts.

As mentioned previously, some TIDieR items may be less relevant to control groups, which could have had an influence on lower ratings among TAU arms. Additional work in this area may help clarify this assertion and determine if a revised or expanded checklist may be needed to aid researchers in reporting the key methodological details of TAU. Additionally, some important methodological aspects of usual care may not currently be captured by the TIDieR checklist. For instance, it may be important to determine if any components of the active intervention condition are present in TAU. Describing the extent to which TAU conditions used in a trial map onto the actual delivered usual care in respective clinical contexts may also be useful for researchers.

The present review identifies issues with reporting on details of TAU control groups in clinical trials of BAIs that limit the internal and external validity of the findings. Although the current consensus that BAIs are efficacious and should be widely implemented in healthcare settings is largely supported by the findings of the reviewed studies, our results highlight a need for more thorough reporting, which can be supported through use of the TIDieR guidelines. It is our hope that this review offers constructive suggestions for researchers conducting BAI trials to strengthen future research on these important interventions that will continue to improve clinical care for at-risk drinkers in healthcare settings.

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